REMARKS

I. Status of the Claims

Claims 11 – 17 are pending. Claims 1 – 10 and 18 – 22 are canceled. No new matter is added.

II. Rejection Under 35 USC 112, first paragraph

Claims 19 – 22 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Without acquiescing to the rejection, and with the intent to facilitate allowance of the application, applicant has canceled claims 19 – 22 without prejudice. Applicant respectfully submits with the cancellation of claims 19 – 22, this rejection is now deemed to be moot.

III. Rejections Under 35 USC 102(b) and U.S.C. 103(a)

Claims 1, 5, 6 and 11 – 18 stand rejected under 35 USC 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Bocan, WO 97/16184. Applicant respectfully traverses this rejection.

As set forth in MPEP 2131, in order to anticipate a claim, the reference must teach every element of the claim. Bocan fails to do so.

Applicant's claimed invention is directed to a method comprising administering atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol by at least by about fifty percent or more from baseline for the prevention or delay of catheter-based revascularization in patients suffering from coronary artery disease in need of such treatment and who have undergone prior angiography .

While Bocan claims a method for regulating lipid concentration by administration of a combination of two compounds; in this instance, (a) an ACAT inhibitor and (b) a HMG-CoA

reductase inhibitor (e.g. atorvastatin), applicant recognizes that there is an arm of the study on page 10 that discloses the administration of atorvastatin alone. However, applicants continue to maintain that Bocan is directed to a different patient population. Bocan teaches the administration of atorvastatin (mainly in combination with an ACAT inhibitor) to patients diagnosed with atherosclerosis or at risk of developing atherosclerosis. Bocan does not teach administering atorvastatin to patients who have undergone a prior angioplasty in order to prevent or delay catheter-based revascularization procedures. Prior to applicant's invention, one skilled in the art would not have concluded aggressive treatment with atorvastatin could obviate the need for surgery. Before the study disclosed in the instant application, it was not known whether aggressive treatment with cholesterol lowering drugs would be more efficacious at reducing the incidence of cardiac events as compared with treatment by catheter-based revascularization procedures. The present invention provides the basis for such a conclusion. Only 13% of patients treated with high doses of a cholesterol lowering drug suffered adverse cardiac events versus 21% of patients whose blockages were cleared with a catheter-based revascularization procedure.

Patients that undergo catheter-based revascularization face risks which are different than that of patients simply being treated to lower their cholesterol. About one-third of patients who undergo surgical revascularization procedures develop restenosis, which is a re-narrowing of the surgically widened segment of the vessel. Restenosis is different from the original stenosis (blocking of a coronary artery) that necessitated the revascularization procedure. Restenosis is a treatment-related condition (iatrogenic) associated with catheter injury to the treated vessel and subsequent proliferative cellular reocclusion of the same vessel. Restenosis is not the same as indigenous or "native" coronary atherosclerosis resulting from cholesterol accumulation in the vessel wall. The reason or mechanism for the development of restenosis is complex and not fully understood. What is clear is that the mechanism is different than that for the formation of the original vessel blockage (stenosis). Restenosis involves the proliferation

of cells including smooth muscle cells whereas stenosis is thought to involve lipid deposition and the inflammatory response. The present invention is an improvement over catheter-based revascularization in that it reduces the risk that the individual will require a surgical procedure thereby reducing the patient's risk of developing restenosis.

The Examiner has alleged that "Bocan discloses the patients have been diagnosed with cardiovascular disease and lesion sizes are compared prior to and after treatment to verify results. See pages 2, lines 16 – 24, 31 – 32 and line 16 of page 11 thru line 7 of page 12." The Examiner further states that it would be clearly obvious if not inherent that prior angiography took place. In reply, applicant points out that the "patients" referred to by the Examiner are rabbits that are used as a model of atherosclerosis (page 9, line 28). The animals undergo a lesion induction phase of 15 weeks followed by an 8-week drug intervention phase. While it is not specifically stated in Bocan, animals are typically randomized and separated into a baseline measurement group and a treatment group. The animals in the baseline group are sacrificed to determine the presence of cardiovascular disease and provide a baseline for size of arterial lesions and a second group which receives treatment. In such a scenario there is no rabbit that is treated that has undergone a prior angioplasty. While we are not able to confirm whether Bocan followed this procedure or surgically treated a rabbit, measured the baseline lesion and then re-introduced the surgically-treated animal into the treatment group, it appears unlikely that this happened. Bocan analyzed the atherosclerosis-treating effects of a combination of (a) an ACAT inhibitor and (b) a HMG-CoA reductase inhibitor (e.g. atorvastatin), and was not measuring the effects of either or both of these drugs in their ability to prevent further surgery in patients who had undergone prior angioplasty.

Therefore, considering the difference in patient population as defined in the amended claims and considering the different problem faced than the one described in Bocan, the claimed invention is clearly novel in light of Bocan.

Since there are known differences in the nature of the problem to be solved between treating patients with atherosclerosis and treating patients who have had an angioplasty in order to prevent or delay catheter-based revascularization procedures, the claimed invention is nonobvious over Bocan.

IV. Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the above amendment and remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 23-0455. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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